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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,732	04/08/2004	Yasuyuki Kawashima	11333/38	1524

7590 05/01/2008

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EXAMINER	
WOOD, AMANDA P	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
05/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,732	KAWASHIMA, YASUYUKI	
	Examiner	Art Unit	
	AMANDA P. WOOD	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-21,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-21 and 25-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 March 2008 has been entered.

Claims 11-21 and 25-26 have been examined on the merits.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-21 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 19-21 and 26, Applicant recites the

phrase “output part.” Applicant does not describe in the instant specification what an “output part” is, and has not clarified as to what would encompass such a part. Furthermore, Applicant does not show in any drawings what an “output part” is and therefore, has not provided sufficient written description to demonstrate to one of skill in the art that they were in possession of the claimed invention.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, first paragraph for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-21 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 19-21 and 26, Applicant recites the phrase “output part.” Applicant does not provide any definition in the instant specification as to what an "output part” would encompass, and does not show such a part in any drawings, other than in a flow chart, and as such, no particular definition for such a part has been provided, and therefore, it is unclear what Applicant means by this phrase.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-15, 17, 19, and 25-26 stand rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda et al (US Patent 6,165,740).

A bacteria measuring apparatus is claimed, comprising a sampling device, a first detector, a second detector, and a control unit.

Fukuda et al disclose a device capable of distinguishing between Staphylococcus and Bacillus bacteria in a sample by analyzing the sample by flow cytometry, wherein the sample stream is irradiated with light, and scattered light and fluorescent light emitted from the particles is detected (see, for example, col. 6, lines 1-15). Cultured Staphylococcus and Bacillus bacteria form different sized aggregates during growth. When analyzed by flow cytometry, the aggregates reflect fluorescent light and scatter other light differently, allowing a sensor to discern between the two types of bacteria (see Abstract; see Summary of the Invention, col. 3 line 61 to col. 4 line 48; see First Embodiment, col. 6 line 25 to col. 8 line 10, as examples). Additionally the unit is equipped with an analysis capability which can diagram particle distributions in two dimensions, from which any required information such as slope of distribution can be measured, reading on instant claims 12-14 (see Fig. 29, for example).

Therefore, the reference is deemed to anticipate the instant claims above.

Response to Arguments

Applicant's arguments filed 19 March 2008 with respect to the 35 U.S.C.102(b) rejection over claims 11-21 and 25-26 have been fully considered but they are not persuasive. In particular, Applicant's arguments that Fukuda et al contains no teaching or suggestion of utilizing fluorescence information as a parameter for creating a scattergram, or of analyzing fluorescence information to obtain a bacteria analysis result, and that Fukuda et al actually teach away from such methods.

The Examiner respectfully disagrees with Applicant's arguments with respect to Fukuda et al.

According to Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987), a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.

Furthermore, according to In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997), "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function" (MPEP 2113). In addition, according to Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original), "[A]pparatus claims cover what a device is, not what a device does."

Therefore, the functional limitations recited by Applicant, which Applicant argues differentiates the claimed invention from Fukuda et al, do not lend patentable weight to the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-21 and 25-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda et al (US Patent # 6,165,740, issued 26 Dec 2000) in view of Kubitschek et al (J Bacteriol, Dec 1986) and in view of Chupp et al (US Pat # 5,631,165, issued 20 May 1997).

A bacteria measuring apparatus is claimed, comprising a sampling device, a first detector, a second detector, and a control unit.

Fukuda et al disclose a device capable of distinguishing between Staphylococcus and Bacillus bacteria in a sample by analyzing the sample by flow cytometry, wherein the sample stream is irradiated with light, and scattered light and fluorescent light emitted from the particles is detected (see, for example, col. 6, lines 1-15). Cultured Staphylococcus and Bacillus bacteria form different sized aggregates during growth. When analyzed by flow cytometry, the aggregates reflect fluorescent light and scatter other light differently, allowing a sensor to discern between the two types of bacteria

(see Abstract; see Summary of the Invention, col. 3 line 61 to col. 4 line 48; see First Embodiment, col. 6 line 25 to col. 8 line 10, as examples). Additionally the unit is equipped with an analysis capability which can diagram particle distributions in two dimensions, from which any required information such as slope of distribution can be measured, reading on instant claims 12-14 (see Fig. 29, for example).

Fukuda does not expressly teach a first detector that determines size information by detecting electrical resistance.

Fukuda does not expressly teach an output part for determining reliability of data, or that outputs a warning when the control unit has determined that identifying bacteria type is difficult.

Kubitschek et al teach that a Coulter-type impedance detector can reliably detect bacterial cell volume. They measure the size determined by impedance counter versus the size determined by pelleting cells and measuring the pellet volume Versus cell Count, and determine that the relationship between actual cell size and cell size determined by Coulter impedance counter is reliably the same (see p. 1466, col. i, paragraph 1; see Fig. 1, pl 1467, for example). Kubitschek et al conclude "the agreement between mean cell volumes measured by the two methods provides evidence that cell volumes determined with the Coulter Counter-Analyzer system are in substantial agreement with the values determined biophysically for the same cells, thereby validating the use of electronic cell sizing for measurements of bacterial volumes" (see p. 1467, col. 2, final paragraph).

Chupp et al teach that a single instrument can comprise both an impedance transducer and an optical flowcell/transducer for detecting light scattering and fluorescence (see "System Overview", col. 11, lines 35-48, for example).

Chupp et al also teach that a system can automatically determine statistical significance of the data it is collecting, and alter its actions based on its determination of statistical significance. For example, when cell counts are low, the apparatus can correct its counting time to improve statistical significance of the data. It would be obvious to include a warning system rather than alter counting times; both involve apparatus determination of statistical, significance and determining a response to the determined significance (see col. 56, lines 25-27, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to arrange an apparatus comprising an optical cytometer and a Coulter impedance counter because Fukuda et al teach that cocci and bacilli can be differentiated by light scattering as well as determination of the volume of the aggregates they form as they grow, Kubitschek et al teach that a Coulter counter can reliably determine bacterial cell volume, and Chupp et al teach that one can combine a Coulter counter and an optical cytometer in a single apparatus.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to arrange a single apparatus for determining bacterial species by combining an impedance analyzer with an optical flow cytometer.

Response to Arguments

Applicant's arguments filed 19 March 2008 with respect to the 35 U.S.C. 103 rejection over claims 11-21 and 25-26 have been fully considered but they are not persuasive. In particular, Applicant's arguments that Fukuda et al contains no teaching or suggestion of utilizing fluorescence information as a parameter for creating a scattergram, or of analyzing fluorescence information to obtain a bacteria analysis result, and that Fukuda et al actually teach away from such methods.

The Examiner respectfully disagrees with Applicant's arguments with respect to Fukuda et al.

According to Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987), a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.

Furthermore, according to In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997), "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function" (MPEP 2113). In addition, according to Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original), "[A]pparatus claims cover what a device is, not what a device does."

Therefore, the functional limitations recited by Applicant, which Applicant argues differentiates the claimed invention from Fukuda et al, do not lend patentable weight to the claimed invention.

Conclusion

No claims are allowed.

Please note that the examiner assigned to the instant application has changed. Accordingly, any inquiry concerning this communication or earlier communications should be directed to examiner Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on Mon-Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
Art Unit 1657

/Robert B Mondesi/
Primary Examiner, Art Unit 1652